

REMARKS

This is a response to the Office Action dated October 9, 2003. Claims 1, 2, 5-8 and 17-19 are pending in this application. Claims 1-3, 5-8 and 17-19 have been rejected by the Examiner. As noted above, Applicants have amended Claims 1, 2, 5, 6 and 8. The amendments are fully supported by the written description. No new matter has been introduced into the application.

Claim Rejections - 35 USC § 102

Claims 1-3 and 17 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Stuffle et al. (U.S. Patent Number 6,067,480). Stuffle et al. is directed to an apparatus for **thermal extrusion** of a polymeric material to manufacture prototype mechanical elements from the polymeric material. See Abstract. In particular, the apparatus is used for deposition of a **liquified ribbon** of the polymeric material in patterned layers which solidify to form a three-dimensional prototype element. See id. As shown in Figure 1, Stuffle et al. discloses that “a cylindrical feed rod 39 of polymeric material is pushed by a piston 40 into a cylinder 41 with a heated head 42 and a discharge nozzle 61.” Col. 4, lines 38-40.

Stuffle et al. fails to disclose all of the elements of amended Claim 1, including an applicator for applying a coating substance to a stent that has:

- a body portion;
- an internal or external atomizing nozzle assembly, including an orifice, extending from the body portion to atomize a spray solution of a polymer, a solvent and a drug; and**
- a temperature controller coupled to the nozzle assembly, **the temperature controller being coupled to the nozzle assembly in close proximity to the orifice and configured to change the temperature of the spray solution as it passes through the orifice** so as to reduce the surface tension or the viscosity of the spray solution sprayed on a stent, wherein the temperature controller is sized to change the temperature of the spray solution at a concentrated area of the nozzle assembly so as to prevent exposure of the spray solution to the change in temperature along the entire length of the body portion to prevent degradation of the drug.

In particular, Stuffle et al. at least fails to disclose (1) an apparatus having an internal or external atomizing nozzle assembly; (2) a temperature controller coupled to a nozzle; or (3) that the

temperature controller is configured to change the temperature of the coating substance as it passes through the orifice. First, Stuffle et al. does not disclose that the thermal extrusion apparatus has an internal or external atomizing nozzle assembly. But, instead, Stuffle et al. only discloses an apparatus that includes a piston that is capable of pushing a polymeric rod to produce a **liquefied ribbon** (not droplets) of polymeric material. See, e.g., Col. 4, lines 38-42. There is nothing in Stuffle et al. that even suggests that the extruding apparatus should include an atomizing nozzle assembly.

Second, referring to Figures 1 and 2 of Stuffle et al., it is clearly shown that the heated head (42) of Stuffle et al. is attached or coupled to the cylinder (41) (i.e., body portion of the applicator), **not** the discharge nozzle (61). This difference in placement is critical to the operation of the Stuffle et al. device – allowing the device to **melt** the polymer feed rod at a high temperature **before** the polymer resin reaches the nozzle. If the polymer feed rod was not melted at a point before the nozzle while operating the Stuffle et al. device, the high pressure caused by piston (40) would likely damage or destroy portions of the device, for example, the passage tip (72).

Moreover, the positioning and the overall characteristics of heated head (42) and heater band (80) of Stuffle et al. clearly dictate that they are not configured to change the temperature of the polymer resin as it passes through the orifice. Instead, the heated head (42) and heater band (80) must be configured to deliver a high temperature to the polymer resin at a position significantly **before** the polymer resin reaches the nozzle.

In short, even though Stuffle et al. disclose that heating generally takes place only at the head (42) to avoid polymer breakdown, the Stuffle et al. apparatus is different than the claimed applicator because the Stuffle et al. apparatus is constructed to provide for a completely different result. In particular, the Stuffle et al. device is configured so that it can **extrude a melted ribbon of polymeric material** from a nozzle apparatus. In order to accomplish this result, the

Stuffle et al. apparatus must be configured in a completely different way than the current invention. Therefore, Claim 1 is allowable over Stuffle et al. Claims 2 and 17 depend from Claim 1 and should be allowable for at least the same reason. Claim 3 has been canceled without prejudice.

Claim Rejections – 35 USC § 103

A. Stuffle et al. In View of Leidner et al.

Claim 3 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Stuffle et al. in view of Leidner et al. (U.S. Patent Number 6,056,993). Without acceding to the propriety of the rejection, Applicants have canceled Claim 3 without prejudice. Therefore the rejection is moot.

B. Leidner et al. In View of Stuffle et al.

Claims 1-3, 5-8 and 17-19 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Leidner et al. in view of Stuffle et al. Leidner et al. is directed to “[a] porous, tubular synthetic prosthesis, prosthesis precursor, and methods of producing the same Specifically the method involves co-spraying both a water soluble and water insoluble **fibrous component onto a mold to form the prosthesis precursor.**” Abstract (emphasis added). Leidner et al. disclosure that “[w]ater insoluble **fibrous component 34** is formed by extruding water insoluble **fiber** forming composition 32 from fiber forming subassembly 40, and water-soluble **fibrous component 35** is formed by extruding water soluble **fiber** forming composition 33 from fiber forming subassembly 41.” Col. 6, lines 12-17 (emphasis added). Leidner et al. also disclose that as part of the method of forming the prosthesis “[t]o help make coating 36 more uniform and smooth, coating 36 **may be heated prior to electrostatic spraying operations.**” Col. 14, lines 30-32 (emphasis added).

1. Prior Art References Do Not Disclose All of the Claimed Limitations

To establish *prima facie* obviousness, **all of the claimed limitations must be taught or suggested** in the references cited. In re Royka, 490 F.2d 981. Leidner et al. and Stuffle et al., alone or in combination, fail to teach or suggest an applicator that comprises

a body portion;
an internal or external atomizing nozzle assembly, including an orifice, extending from the body portion to atomize a spray solution of a polymer, a solvent and a drug; and
 a temperature controller coupled to the nozzle assembly, **the temperature controller being coupled to the nozzle assembly in close proximity to the orifice and configured to change the temperature of the spray solution as it passes through the orifice** so as to reduce the surface tension or the viscosity of the spray solution sprayed on a stent, wherein the temperature controller is sized to change the temperature of the spray solution at a concentrated area of the nozzle assembly so as to prevent exposure of the spray solution to the change in temperature along the entire length of the body portion to prevent degradation of the drug

as recited by amended Claim 1. As noted above, Stuffle et al. fail to disclose all the limitations of Claim 1. Moreover, Leidner et al. do not disclose an apparatus that includes an internal or external atomizing nozzle assembly, but only disclose an apparatus having plungers that are used to extrude **continuous fiber components 34 and 35**. See, Col. 6, lines 1-39 and Figures 1 and 6. Also, with respect to controlling the temperature of the fiber components, Leidner et al. merely disclose that the coating “may be heated prior to electrostatic spraying operations” (col. 14, lines 31-32), or that “[m]andrel 12 and prosthesis 9 may be heated during winding operations, if desired. For example, a 250 watt IR lamp can be placed about 190 mm **away from mandrel 12** for this purpose.” Col. 12, lines 28-31 (emphasis added). Nowhere in Leidner et al. is it disclosed that a temperature controller is coupled to a nozzle in close proximity to an orifice and configured to change the temperature of a coating substance as it passes through the orifice. Instead, Leidner et al. only disclose that the coating may be heated prior to an application process or that the mandrel and prosthesis can be heated **from a distance**. Accordingly, Claim 1 is

allowable over Leidner et al. in view of Stuffle et al. Claims 2 and 17 depend on Claim 1, and are allowable for at least the same reason. Claim 3 has been canceled without prejudice.

Additionally, Leidner et al. and Stuffle et al., alone or in combination, fail to teach or suggest all of the claimed limitations of amended Claim 5. In particular, the references fail to teach or suggest an apparatus that comprises

(a) **an applicator capable of spraying atomized droplets of a composition containing a drug at a stent;** and

(b) a temperature controller connected to the applicator and configured to adjust the temperature of the composition to a temperature other than ambient temperature to reduce the surface tension or the viscosity of the composition sprayed on the stent, and configured to adjust the temperature of the composition **in a concentrated area during the coating process to prevent prolonged thermal exposure of the composition to prevent degradation of the drug.**

First of all, the prior art references at least fail to disclose an applicator that is capable of spraying droplets of a composition. Both references, instead, are specifically directed to **extruders**¹. For instance, Leidner et al. merely describe and show (e.g., in Figures 1 and 6) an apparatus that is capable of extruding a fibrous component as opposed to droplets of a composition. See Col. 6, lines 12-17 (“[w]ater insoluble fibrous component 34 is formed by extruding water insoluble fiber forming composition 32 from fiber forming subassembly 40, and water-soluble fibrous component 35 is formed by extruding water soluble fiber forming composition 33 from fiber forming subassembly 41.”) Although Leidner et al. disclose a coating 36 that can be applied by brushing, dip coating, and spraying (see col. 14, line 47), there is absolutely no description of the apparatus that can be used to apply coating 36. See Col. 14, line 67 to col. 15, line 2 (“[o]nce coating 36 is formed on mandrel 12, **electrostatic spraying operations may be carried out as described above with respect to FIG. 1**”) (emphasis added).

¹ “Extrusion” is “a fundamental processing operation in many industries in which a material is forced through a metal forming die, following by cooling or chemical hardening. The material may be liquid (molten glass or a polymer dispersion); a viscous polymer, as in injection molding; a semi-solid mass, such as a rubber or plastic mix; or a hot metal billet.” Richard J. Lewis, Hawley’s Condensed Chemical Dictionary, 505 (Van Nostrand Reinhold, 12th Edition, 1993).

The only apparatus that is described by Leidner et al. is the one that is used to **extrude** the fibrous component—a component shaped like a long string or tube (e.g., fibrous components 34 and 35 of Figures 1 and 6), not a droplet.

Stuffle et al. also fail to disclose an applicator capable of producing droplets for spraying onto a stent. Stuffle et al. merely disclose an apparatus for thermal extrusion of a polymeric material to manufacture a prototype. See Abstract. In particular, Stuffle et al. only disclose “a cylindrical feed rod 39 of polymeric material is pushed by a piston 40 into a cylinder 41 with a heated head 42 and a discharge nozzle 61. A **discharge ribbon of extruded material** flows onto a moving, heated platform 43 to form a prototype or mechanical element 44.” Col. 4, lines 38-42 (emphasis added). There is nothing in Stuffle et al. that remotely suggests that the extruder could be capable of applying droplets of the material. Accordingly, Claim 5 is allowable over Leidner et al. in view of Stuffle et al. Claims 7, 8, 18 and 19 depend on Claim 5, and are allowable for at least the same reason.

2. There Was No Motivation to Combine the References

In addition, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness because there would have been no suggestion or motivation to modify Leidner et al. with the teachings of Stuffle et al. in order to make the claimed invention. There are three possible sources for a motivation to combine references: “the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art.” In re Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998). However, the mere fact that a prior art reference can be modified does not make the modification obvious unless the prior art also suggests the desirability of the modification. See In re Gordon, 733 F.2d 900, 902 (Fed. Cir. 1984). Moreover, the suggestion or motivation to make the claimed combination **must be found in the prior art, and not based on applicant’s disclosure**. See In re Vaeck, 947 F.2d 488, 493 (Fed. Cir. 1991).

First, there was no evident desirability to modify the Leidner et al. reference based on the nature of the problems to be solved. Some of the relevant problems include uneven coatings on stents, the formation of “cob webs” and “pool webs” on the surface of stent struts, and prolonged thermal exposure of a composition that can lead to the degradation of components of the composition such as thermally sensitive drugs. Neither Leidner et al., nor Stuffle et al. provide any suggestion that that they were concerned about the problems of atomized droplet size, “cob web” formation between stent struts, excessive gathering of clumps or “pool webs” of coating on the surface of the stent struts, or the prolonged thermal exposure of a coating substance having a drug.

Secondly, the disclosures of the prior art references do not provide any suggestion that it would have been desirable to combine the references to make the claimed invention because the references are directed to fields of art that are completely different than the claimed invention. Applicants respectfully submit that one of ordinary skill in the art of coating stents would not have had any motivation to look to the technology disclosed in Leidner et al. or Stuffle et al. to form the claimed invention. In particular, there is no suggestion or hint in the prior art references that one of ordinary skill in the art would have looked to the art of polymeric extruders to produce the claimed invention. Thus, it appears the Examiner has combined two references completely outside of the field of art practiced by the present invention.

Furthermore, the prior art references teach away from a combination to make the claimed invention. Leidner et al. disclose that as part of the method of forming the prosthesis “[t]o help make coating 36 more uniform and smooth, coating 36 **may be heated prior to electrostatic spraying operations**. Preferably, coating 36 may be heated to a temperature close to, more preferably slightly above, the glass transition temperature of the material(s) constituting coating 36 so that the material of coating 36 at least partially melts to provide a smooth, even, uniform coatable surface upon which to form prosthesis 9” (col. 14, lines 30-38) (emphasis

added). The above quotation from Leidner et al. indicates that Leidner et al. teach that the coating solution should be heated to a high temperature (e.g., the glass transition temperature of the material). As a result, Leidner et al. actually teach away from an apparatus that is configured to **prevent prolonged thermal exposure** of a coating substance as the coating substance is being applied to a stent. Therefore, one of ordinary skill in the art would not have had any motivation to modify the Leidner et al. reference and as such, the Examiner has failed to establish a *prima facie* case of obviousness.

3. Applicants Have Shown Superior Results

Applicants reiterate that the claimed invention has shown superior results which require a finding that the claimed invention was not obvious to one of ordinary skill in the art. It is well established in patent law that an applicant can rebut a *prima facie* case of obviousness by offering evidence of “secondary considerations.” See, *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1965). Rebuttal evidence may include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. See, *In re Dillon*, 919 F.2d 688, 692-93 (Fed. Cir. 1990). As noted in the Response dated January 17, 2003, Applicants’ invention has addressed some of the long-felt problems associated with **coating stents**. In particular, Applicants have clearly demonstrated that the claimed invention yields improved properties which alleviate problems such as the formation of polymer “cob webs” between the stent struts, excessive gathering of clumps or “pool webs” of coating on the surface of the stent struts, and lack of uniformity of the coating.

Furthermore, Applicants reiterate that the prior art references do not address the problems of coating stents. The prior art references do not provide any objective evidence that they have solved the problems of “cob web” formation between stent struts, nor have they solved the problem of excessive gathering of clumps or “pool webs” of coating on the surface of the stent struts. Leidner et al., for instance, merely propose that “coating 36 may be heated to a

temperature close to, more preferably slightly above, the glass transition temperature of the material(s) constituting coating 36 so that the material of coating 36 at least partially melts to provide a smooth, even, uniform coatable surface upon which to form prosthesis 9" (col. 14, lines 30-38) (emphasis added). Because Applicants have clearly demonstrated that the claimed invention has shown superior results, Applicants respectfully request the Examiner to reconsider the finding of obviousness.

B.



CONCLUSION

Claims 1, 2, 5-8 and 17-19 are pending in this application. Examination and allowance of the claims are respectfully requested. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0345.

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